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Davide R. Grassetti

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EXAMINER

WANG, SHENGJUN

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/044,463
Filing Date: January 10, 2002
Appellant(s): GRASSETTI ET AL.

Gary Baker
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 29, 2009 appealing from the Office action mailed August 17, 2009.

(I) (1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

US Patent 4,378,364 Grassetti March 29, 1983

Olive et al. "T cell Immune Response to Cancer in Human and its Relevance for Immunodiagnosis and Therapy," Cancer Surveys, 1992, Vol. 13, pages 173-204.

Tagawa "Cytokine therapy for cancer," Current Pharmaceutical Design, 2000, Vol. 6, pp 681-699.

(9) Grounds of Rejection

Claim Rejections 35 U.S.C. 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims are directed to a method comprising administer the disulfide compounds herein to an individual in need of immune response modulation. Examples of those individuals are given in the specification, paragraphs 0095-0102, e.g., immune compromised patients (0100), patients with Lentivirus infection (paragraph 0099) is one of the examples. The effective amounts are defined as about 10 µg to about 5 g per kg of body weight (0087).

2. Claims 1-2, 5-6, 10-12, and 20-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Grassetti (US 4,378,364, IDS), as evidenced by Oliver, and Tagawa.

3. Grassetti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas comprising administering to the patients an effective amount of 6,6'-

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dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day.

The Patients treated in the examples include those have surgery, chemotherapy, and/or metastases, See, particularly, the examples, the abstract and the claims. Grassetti particularly teaches the administration of 6, 6'-dithiodinicotinic acid at the time of surgery for cancer.

Grassetti reasons that "It is known that the manipulation of a tumor during surgery cause large number of cancer cells to enter the blood stream with concomitant high danger of formation of metastases. Treatment with the reagent should be continued for an adequate period of time both before and following surgery until the *natural defenses* of the organism have destroyed the remaining circulating cancer cells." See, column 11, lines 52 to column 12, line 8. As to "modulating an immune response," or other limitations that further define the immune response (claims 10-12), recited in the preamble, it is noted that preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

4. The step in the claimed method: "identifying an individual in need of immune response modulation;" is inherently met by the method of treating cancer patient disclosed in the reference, as cancer patients, particularly, those who have surgery or under chemotherapy are recognized as "in need of immune response modulation" See, particularly, the abstract in Tagawa and page 198 in Oliver. Oliver specifically states: "All modalities of cancer therapy

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except hormone therapy (i.e., surgery, radiotherapy and chemotherapy) suppress immune responses.”

5. Further, appellants’ attention is directed to *In re Swinehart*, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated “is elementary that the mere recitation of a newly discovered function or property, inherently possessed by thing in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.” In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds, i.e., treating cancer patient who is in need of immune potentiation, is old and well known rendering the claimed subject matter anticipated by the prior art.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 5-6, 10-12, and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grasseti (US 4,378,364, IDS), in view of Oliver, and Tagawa. .

8. Grasseti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas comprising administering to the patients an effective amount of 6,6'-dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day. The Patients treated in the examples include those have surgery, chemotherapy, and/or metastases, See, particularly, the examples, the abstract and the claims. Grasseti particularly

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teaches the administration of 6, 6'-dithiodinicotinic acid at the time of surgery for cancer.

Grassetti reasons that "It is known that the manipulation of a tumor during surgery cause large number of cancer cells to enter the blood stream with concomitant high danger of formation of metastases. Treatment with the reagent should be continued for an adequate period of time both before and following surgery until the *natural defenses* of the organism have destroyed the remaining circulating cancer cells." See, column 11, lines 52 to column 12, line 8. As to "modulating an immune response," or other limitations that further define the immune response (claims 10-12), recited in the preamble, it is noted that preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

9. Grassetti does not teach expressly the steps for "identifying an individual in need of immune response modulation;"

10. However, Oliver specifically states: "All modalities of cancer therapy except hormone therapy (i.e., surgery, radiotherapy and chemotherapy) suppress immune responses." See, page 198. Tagawa teaches that modulation of immune response is one of the strategies for cancer therapy. See, particularly the abstract.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to first identify a patient in need of immune modulation, such as cancer patients under surgery, or immediate before or after the cancer

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surgery, and/or with chemotherapy, and administer the patients a sufficient amount of 6,6'-dithiodinicotinic acid as taught by Grasseti.

A person of ordinary skill in the art would have been motivated to first identify a patient in need of immune modulation, such as cancer patients under surgery, or immediate before or after the cancer surgery, and/or with chemotherapy, and administer to the patient a sufficient amount of 6,6'-dithiodinicotinic acid as taught by Grasseti because cancer patients, particularly, those under surgery and/or chemotherapy, are known to be in need of immune modulation, and 6,6'-dithiodinicotinic acid is known to lessen pain and increase well-being of cancer patients, particularly, those having surgery and/or chemotherapy. Further, 6, 6'-dithiodinicotinic acid is taught to maintain or improve the natural defense (immune system) and to keep the cancer cells released during the surgery under control.

(10) Response to Argument

11. With respect to the rejections under 35 U.S.C. § 102 (b), appellants contend that cited Grasseti reference does not teach all the limitations set forth in the claims, particularly, Grasseti does not particularly “identify” cancer patients, such as chemotherapy-treated cancer patients, as “in need of immune response modulation.” The arguments are not tenable. Grasseti teaches a method of lessening the pains and increasing the well-being of patients with carcinomas comprising administering to the patients an effective amount of 6,6'-dithiodinicotinic acid, wherein the preferred amounts is about 500 mg to about 900 mg per day. The *Patients treated* in the examples include *those have surgery, chemotherapy, and/or metastases*. See, particularly, the examples, the abstract and the claims. Grasseti particularly teaches the administration of 6, 6'-dithiodinicotinic acid at the time of surgery for cancer. Grasseti reasons that "It is known that

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the manipulation of a tumor during surgery cause large number of cancer cells to enter the blood stream with concomitant high danger of formation of metastases. Treatment with the reagent should be continued for an adequate period of time both before and following surgery **until the natural defenses of the organism have destroyed the remaining circulating cancer cells.**"

See, column 11, lines 52 to column 12, line 8. Therefore, Grasseti particularly identifies those in need of immune response modulation, i.e. increase or maintain natural (immune) defenses.

Oliver specifically states: "All modalities of cancer therapy except hormone therapy (i.e., surgery, radiotherapy and chemotherapy) suppress immune responses." See, page 198. Tagawa teaches that modulation of immune response is one of the strategies for cancer therapy. See, particularly the abstract. Therefore, the identification of patients having surgery or chemotherapy is a step of identifying patients who is in need of immune response modulation.

12. Appellants' remarks about col. 12, line 4 of Grasseti are not persuasive. Grasseti teaches specifically those cancer patients having surgery should be treated with 6, 6'-dithiodinicotinic acid until "the natural defenses" (immune system) destroy all the cancer cells leaked into blood stream during the surgery. 6,6'-dithiodinicotinic acid is needed for modulating the immune response as immune response in patients with surgery and chemotherapy is compromised (Oliver).

13. The "modulation of immune response" is given patentable weight only to the extent that it defines the patient population. Such function would be inherent in the method of Grasseti, as one is administering the same compound, i.e., 6, 6'-dithiodinicotinic acid, to the same group of patients, cancer patients having surgery or chemotherapy. See *Perricone v. Medicis Pharmaceutical Co.*, 432 F.3d 1368, 1377-78, 77 USPQ2d 1321, 1328 (Fed. Cir. 2005) (noting

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that the realization of a new benefit of an old process does not render that process patentable); see also *Bristol-Myers Squibb Co. v. Ben Venue Laboratories*, 246 F.3d 1368, 1376, 58 USPQ2d 1508,1514 (Fed. Cir. 2001) (stating in the context of a claimed process that was drawn to the same use comprising the same steps of the prior art, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent.").

14. As to the rejections under 35 U.S.C. 103, appellants contend that the examiner mischaracterizes the teachings by Grassetti. (col. 12, line 4). The examiner respectfully disagrees. What Grassetti stated is

It is known that manipulation of a tumor during surgery causes large numbers of cancer cells to enter the blood stream with concomitant high danger of formation of metastases. Treatment with the reagent should be continued for an adequate period of time both before and following surgery until **the natural defenses of the organism** have destroyed the remaining circulating cancer cells. (col. 11, line 54 to col. 12, line 8).

Appellants do not dispute that the "defense" means immune system of the organism, but rather argue that "NATURAL defenses" means an immune system without any sort of modulation.

This is a bold, but incorrect twist of the concept of "the natural defenses of the organism." Since Grassetti teaches that the treatment with TFDs is to improve the well-being, not to kill the cancer cells, and it is known in the art that surgery and chemotherapy will weak the immune response or negatively modulate the immune response, Grassetti's statement clearly suggests that treatment with TEDs is beneficial to *the natural defenses of the organism*.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Shengjun Wang/

Primary Examiner, Art Unit 1627

Conferees:

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